

MECHLENGURG et al. -- Appln. No.: Not Yet Assigned  
(CONT. of 09/761,788)

## AMENDMENTS TO THE SPECIFICATION

Please replace the title of the invention on page 1, line 1, with the following new title:

MUSCLE STIMULATING DEVICE AND METHOD FOR ~~DIAGNOSING AND TREATING~~  
~~A BREATHING DISORDER~~

After the title and before the section heading "BACKGROUND OF THE INVENTION", insert the following section heading and new paragraph.

### --CROSS REFERENCES TO RELATED APPLICATIONS

This is a Continuation of U.S. Patent Application No. 09/761,788 filed on January 17, 2001, under 34 U.S.C. § 120, which is a Divisional of U.S. Patent Application No. 09/173,871 filed on October 16, 1998 under 35 U.S.C. § 120, abandoned, which claims priority under 35 U.S.C. § 119(e) from U.S. Provisional Patent Application No. 60/062,288 filed October 17, 1997.--

Please replace the paragraph beginning at page 8, line 1, with the following rewritten paragraph.

Figs. 8A and 8B illustrate a fifth embodiment and Fig. 8C illustrates a sixth embodiment for the coil in the collar;

Please replace the paragraph beginning at page 25, line 14, with the following rewritten paragraph.

Fig. 8C illustrates a sixth embodiment for the coil. Coil 111 in this figure is similar to the coil configuration shown in Figs. 4-6 except that one of the large loops have been deleted, leaving a three-loop coil with two areas 113 of field strength summation. This coil configuration is advantageous in that is-it reduces the coil resistance and inductance as compared to the coil of Figs. 4-6.

Please replace the paragraph beginning at page 37, line 10, with the following rewritten paragraph.

The present invention also contemplates providing a safety feature in which a maximum stimulation energy that can be provided to the patient is set. This can be accomplished via a control unit. This stimulation energy provided to the patient will not ~~be~~ exceed the set maximum regardless of the stimulation energy set by the user on the control unit. It is preferable that the means by which the maximum stimulation energy is set is secured so that it cannot be altered inadvertently, or tampered with. The use of a password that must be input in order to alter the maximum setting is an example of such a security feature.

Please replace the paragraph beginning at page 37, line 10, with the following rewritten paragraph.

In still another embodiment of the present invention, the magnetic stimulation system is provided with an automatic turn-on and/or an automatic turn-off feature. This provides the advantages of simplifying the operation of the system and conserving power, for example.

Sensors on the collar, ~~for example~~, such as a temperature sensor or galvanic type sensor, can detect when the appliance is disposed on the patient. The output of these sensors ~~are~~is used to control the actuation and deactivation of the stimulation system ~~of~~or the application and cessation of the stimulation therapy.

Please replace the paragraph beginning at page 42, line 4, with the following rewritten paragraph.

Another embodiment of the present invention contemplates using the magnetic stimulating system in conjunction with a conventional pressure support system that applies positive air pressure at the mouth and/or nose of the patient to "splint" the airway. Even if magnetic stimulation of the muscles of the airway does not fully open the airway, it is believed that the induced muscle stimulation will reduce the pressures necessary to be provided by the pressure support system in order to splint the airway and treat the breathing disorder. It is well recognized that the pressure needed to be provided to the patient by the pressure support device to treat the breathing disorder should be kept as low as possible.

Please replace the paragraph beginning at page 42, line 12, with the following rewritten paragraph.

The present invention contemplates that the magnetic stimulating system of the present invention can be used in conjunction with most, if not all, conventional ~~the~~ pressure support systems. Such pressure support systems typically include a pressure generator 172 that generates a gas flow, a conduit 173 that carries the gas flow to the patient, and a patient interface device 174 that communicates the conduit with the patient's airway. See Fig. 14. Examples of

pressure support devices that are used in conventional pressure support systems include a CPAP (continuous positive airway pressure) device, bi-level devices, which provide variable levels of pressure support during the patient's respiratory cycle, such as the Respiration BiPAP® devices, PAV® devices and PPAP devices. Examples of suitable patient interface devices include nasal masks, oral appliances, nasal/oral masks, full face masks, hoods, nasal cannulas, trachea tube, and any other device that communicates communicates a gas flow with the patient's airway.

Please replace the paragraph beginning at page 44, line 5, with the following rewritten paragraph.

Fig. 14 illustrates an example of a system 170 for diagnosing the likelihood that a subject suffers from OSA using the magnetic stimulator discussed above. Diagnosis system 170 includes a CPAP device 172 for providing continuous positive airway pressure to the patient's airway via a nosemask 174 or other suitable nose sealing member. Magnetic stimulator 30 induces tension in the subject's upper airway muscles. An acoustic transducer 176 measures the subject's compliance, i.e., the change in the cross-sectional area, and hence the volume, of the patient's upper airway. It is to be understood that other devices for measuring the subject's compliance, such as through magnetic resonance imaging (MRI), are contemplated by the present invention. An acoustic transducer is used for this purpose in the illustrated embodiment because of its relative simplicity, ease of use and low cost. In the illustrated embodiment, CPAP device 172, acoustic transducer 176 and magnetic stimulator 30 are all operated under the control of a computer 178. Also, a monitor 180 and keyboard 182 are coupled to computer 178.

Please replace the Abstract of the Invention beginning at page 57, line 3, with the following rewritten paragraph.

A device and method for magnetic stimulation of muscles for the ~~diagnosis and~~ relief of a breathing disorder, such as obstructive sleep apnea is disclosed. Magnetic stimulation is used to stimulate muscles which serve to stabilize the upper airway of an individual whose nocturnal apneic events are related to diminished muscle tone. In one embodiment, A-a sensor monitors a physiologic characteristic of the patient, a coil is energized to stimulate the appropriate muscles associated with the upper airway, a power supply provides power for energizing the coil, and a control system controls the application of power to the coil based on the output of the sensor. A passive probe is provided in the patient to focus the magnetic field produced by the coil. ~~Diagnosis of obstructive sleep apnea is accomplished by measuring the subject's compliance in the presence and absence of the magnetic stimulation of the upper airway muscles. The smaller the difference between these two compliance levels, the more likely that patient suffers from obstructive sleep apnea.~~